

REMARKS

**1. Claim Rejections -- 35 U.S.C. § 103**

Claims 1-10, and 12-13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 5,228,491 to Moniz (hereinafter referred to as “Moniz”) in view of WIPO Publication No. WO 01/15553 to Nair et al. (“Nair”) and U.S. Pat. No. 6,254,913 to Wadsworth et al. (“Wadsworth”). Applicants appreciate the concerns raised by the Examiner, but respectfully submit that in light of the amendment to the claims as set forth above and the arguments presented below, neither Moniz, Nair, or Wadsworth, either individually or collectively, render the claims of the present invention, as amended, obvious.

Applicants specifically address the Examiner’s contention that limiting dosage amounts of *Morinda citrifolia* is inherent in the art and that the claims of the present invention make no recitation of any specific dosage amounts. In response to this contention, which serves as the basis for the rejection of the claims, applicants submit that the claims have been amended to make more specific the recitation of providing a dosage to a patient. Specifically, claims 1, 9, and 12 have been amended to recite that the dosage is to be administered two to three times per day in an amount between about 2 and 3 ounces. The claims have further been amended to recite that this specific dosage amount is not arbitrary, but dependent upon several factors, such as the age, body weight, health, sex, diet, and other similar factors of the patient, as well as the time and route of administration, the rate of excretion, the drug combination, and the severity of the particular disease being treated. Each of these amendments have support in the specification. See Specification, pg. 13. As such, Applicants have amended the claims to recite specific parameters surrounding the dosing of *Morinda citrifolia*.

With regards to the Moniz, Nair, and Wadsworth references, none of these references, either individually or in combination, teach the specific dosage parameters recited in the amended claims. Specifically, neither Moniz nor Nair teach or suggest to specifically administer between 2 to 3 ounces of Morinda citrifolia two to three times daily for effective inhibition of cyclooxygenase. Moreover, through several tests, it has been discovered that 2 to 3 ounces of Morinda citrifolia administered 2 to 3 times daily is effective at inhibiting cyclooxygenase. And, as stated by the Examiner, dosages are typically not arbitrary as a larger dosage is not always better, or on the contrary, a decreased dosage isn't always less effective. As such, the specific dosage included in the claims, as amended, function as the proper amount of Morinda citrifolia needed to effectively inhibit cyclooxygenase. And, although this dosage may be varied, as stated in the claims depending upon the several factors, the dosage is limited to preferably be between 2 to 3 ounces.

In light of the foregoing, as there is nothing in the prior art references that teach or suggest the specific dosage recited in the claims, Applicants respectfully request that the claims of the application be reconsidered and that the rejection under § 103 be withdrawn.

Each of the dependent claims place further limitations on what is otherwise argued allowable subject matter. Therefore, Applicants respectfully submit that these claims also stand in a condition for allowance.

CONCLUSION

Based on the foregoing, Applicant respectfully submits that the deficiencies in the application have been corrected and that the proposed claims are not rendered obvious by the prior art references cited by the Examiner. As such, Applicant believes that the claims are now in a condition for allowance, and action to that end is respectfully requested.

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

DATED this 30 day of June, 2003.

Respectfully submitted,

  
KIRTON & MCKONKIE

Michael F. Krieger  
Attorney for Applicant  
Registration No. 35,232

KIRTON & MCKONKIE  
1800 Eagle Gate Tower  
60 East South Temple Street  
Salt Lake City, Utah 84111  
(801) 328-3600 telephone  
(801) 321-4893 facsimile

CLJ:lah

#692788 v1 - Response to 05/01/03 PAT OA